The Royal New Zealand
College of General Practitioners
Te Whare Tohu Rata o Aotearoa

17 April 2019

Our Ref: BC19-605

Pamela Randell
Ministry of Health
PO Box 5013
WELLINGTON 6140

By email: therapeuticproducts@moh.govt.nz

Dear Pamela Randell

Draft Therapeutic Products Bill

Thank you for giving The Royal New Zealand College of General Practitioners the opportunity to comment on the draft **Therapeutic Products Bill**. The College largely supports the new scheme; however, we do have some concerns over controlled activities and Direct to Consumer Advertising (DTCA) which are set out in our submission.

Submission

The College's submission is formatted under key relevant questions from the consultation document and follows the questions in numeric order.

The following general principles have guided the College's work on this submission:

- any medication or device claiming a therapeutic benefit should be safe and subject to regulation;
- any natural product claiming a therapeutic benefit should be safe and subject to regulation;
- patients should receive health information on therapeutic products from an independent source and
- regulations on pharmacy ownership should enable models of integrated care

A1 Do you support the general design of the new regulatory scheme for therapeutic products?

The College agrees with the high-level principles of the new regulatory scheme for therapeutic products, specifically:

(a) the likely benefits of therapeutic products should outweigh the likely risks associated with them;
(b) regulation of therapeutic products should— (i) be proportionate to the risks posed by the products; and (ii) support the timely availability of therapeutic products;
(c) the administration of this Act should be carried on in an open and transparent manner; and
(d) there should be co-operation with overseas regulators, compliance with international obligations, and, if appropriate, alignment with international standards and practice.

However, we do have several concerns about the draft bill. These relate to:

- the exclusion of natural health products;
- inclusion of Direct to Consumer Advertising;
- medicine classification;
- off-label prescribing; and
- extended role of health practitioners.

The College notes that the regulations and rules will make up a significant part of this regulatory regime, and as such we would like to be consulted in the design of these parts of the regime.

Natural Health Products

The College has already expressed its concerns over the lack of regulation of natural health products in its submission to the Health Select Committee on the Natural Health Products Bill.[1]

In addition, the definition of therapeutic purpose in this draft Bill overlaps with that of natural health products in some cases. In practise, this is likely to make it difficult for regulators and practitioners to decide which products fit into each regime. This lack of clarity is further complicated by a potential separate regime for cannabis products.

The College submits there should be one regulatory regime covering natural health products, therapeutic products and medicinal cannabis products to create a system that is easy for practitioners to understand and prevent unintended overlaps and gaps, rather than make things overly complex.

B1 Please provide any comments on the purpose or principles of the Bill (ss 3 and 4)

The College agrees with the purpose of the Act to protect personal and community health. This purpose is useful when considering what is included in the Bill, especially the continued inclusion of Direct to Consumer Advertising (DTCA). There is extensive research showing that DTCA is harmful to personal and community health; as such the College is advocating for DTCA to be prohibited in New Zealand and replaced with an independent health resource.[2]

B2 Please provide any comments on the definitions or meanings set out in the draft Bill (ss 14–50)

The College would like clarification on how the definition of therapeutic purpose relates to natural health products, as some products may fit under the definition of therapeutic purpose.

C2 Please provide any comments on the approach for medicines categorisation (classification)

Role of the regulator

The College needs more information to comment on the classifications of medicine. The proposed framework in the Bill is heavily reliant on the regulator and the expert community. The regulator and expert community would need to carefully balance access to medications, alongside the risk profiles.

Process of reclassifying medicines

Currently, stakeholders can comment on reclassifications and the College would like this to continue, however, this process needs to be more robust, in particular notifying relevant stakeholders of changes to medications. The College has noted in several past submissions to the Medicines Classification Committee (MCC) that notice of consultation has not given stakeholders enough time or respond, or in some cases has not notified stakeholders at all.

Medicine classification follows the same order as the Australian Government's classification system

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[1] https://oldgp16.rnzcgp.org.nz/assets/New-website/Advocacy/18Submission-to-MOH-re-The-Regulation-of-natural-Health-Products.pdf

[2] https://oldgp16.rnzcgp.org.nz/assets/New-website/Advocacy/Position-Statements/2017.03-DTCAPositionStatement.pdf

The College recommends that the medicine classification follows the same as the Australian Government's classification. As such we recommend the classification changes from:

- prescription medicines (category 1);
- pharmacist medicines (category 2);
- pharmacy medicines (category 3);
- general-sale medicines (category 4)

To:

- general sale (category 1)
- pharmacist medicines (category 2)
- pharmacy medicine (category 3)
- prescription medicines (category 4)

Although Australia and New Zealand have separate legislation, New Zealand tends to follow similar categorisation as Australia and aligning the categories will help mitigate any confusion caused when classifying drugs.

C11 Do you think that products that have similar features and risks to medical devices, but are not for a therapeutic purpose, should be regulated? If so, are there particular products you are concerned about and why?

The College supports regulation of medical devices that present a risk to consumers, even if those devices do not have a therapeutic purpose. This would be consistent with the Bill's stated purpose to protect personal and community health.

The College would also like clarity on whether vaping devices will be covered under this Bill. These devices are of interest as they tend to promote a therapeutic purpose but may also cause harm to the consumer.

C18 What do you think of the approach to curtail the personal importation of prescription medicines via the post and courier, meaning most unapproved prescription medicines imported from overseas would need to be sourced by the issuer of the special clinical needs supply authority, a pharmacy, or a wholesaler?

The College agrees with the Ministry's proposal that the personal importation of medicine should be curtailed. We agree with the exception that people can bring in prescribed personal use medicines (prescription and non-prescription) with them when they come into New Zealand.

C20 Do the current pharmacy licensing requirements create any other barriers to the development and delivery of innovative pharmacist services involving medicines?

The College would like more information on how pharmacy license requirements would affect the development of integrated models of care. We have some concerns that licensing requirements may restrict patients' access to dispensed medications.

> *"I am a solo rural practitioner…dispensing GP. My patients would benefit substantially if I could dispense directly to them, our closest pharmacy is over 50km away & after 11.30 am there is no practical way for the patients to get their prescription filled till the next day. I have to carry MPSO [Medical Practitioner Supply Order] to cover important items. Even on the day the rural patients have to return to the pharmacy depot after 3pm to get their items."*

Co-ownership of pharmacies and general practices

The College also has concerns over controls of joint ownership of pharmacies and general practice. There seems to be a focus on preventing owner-prescribers having financial benefit from the prescription but little concern over owner-pharmacists influencing general practice employees. These conflicts of interests need to be managed both ways, while also ensuring equitable services. Patients should not face barriers when accessing medicines but nor should they be exploited for financial gain.

C43 Do you have any comments on the arrangements for establishing the authority to prescribe via the relevant health practitioners' scope of practice (subject to approval from the Minister of Health)?

The College agrees with the health practitioner scope to explicitly state prescribing and the ability to do standing orders. However, any changes that would allow other scopes to issue standing orders in a scope they do not currently prescribe in would need to be consulted on, as with any other changes to the Health Practitioners Competency Assurance Act (2003).

The College agrees there needs to be more consistency as the way this prescribing authority is set up for different prescriber groups. However, the College does have concerns over the proposed approach of referencing another piece of information in the Act, as this makes it difficult for health professionals and patients to access. We would suggest the Ministry continues working with stakeholders on this piece of work.

C44 Do you think regulations should be developed to require a consistent approach to the form and content of prescribing provisions within scopes of practice?

The College agrees with a consistent approach to prescribing and would like GP involvement in the development of these regulations.

C45 Please provide any comments on the approach to standing orders. (Note that the detailed requirements for standing orders will be specified in regulations and consulted on at a later stage.)

The College would like to register our interest in being involved in developing regulations for standing orders.

C46 What do you think about the approach for the off-label use of medicines that have been approved in New Zealand?

Currently, the draft Bill suggests adding a tick-box for any off-label drug use by a prescriber. The College has concerns about this approach as it may create unnecessary work for general practitioners. Off-label prescribing is common in general practice.

The College would also like to know the rationale for collecting this data as an off-label prescription does not necessarily represent a risk to patient safety or unnecessary prescribing.

C50 Do you consider health practitioners should be authorised to supply pharmacy (category 3) medicines to their patients? What are the benefits and/or risks of allowing this?

There are two benefits to allowing health practitioners to supply pharmacy medicines to their medicines:

- it may reduce barriers to accessing medication, particularly where patients have to travel some distance to fill their prescriptions; and
- it may help some patients increase compliance with their treatment plan.

However, our members also pointed out key risks, including:

- a surge in antibiotic use,
- polypharmacy,
- conflicts of interest if the prescriber also benefited from the transaction, and
- that some diagnoses may be missed.

If the Ministry were to allow health practitioners to prescribe medicine, the following controls would need to be in place:

- appropriate level of experience, well documented notes and is appropriate to the scope of practise;
- audit for prescribers; and
- clear statement that prescribers were not able to benefit from the transaction.

Furthermore, the expansion would also depend on what the health practitioner was prescribing; for example, podiatry might be a relatively simple example compared with category 3 medicines being supplied for mental health conditions.

C53 Do you have a view on whether direct-to-consumer advertising of prescription medicines should continue to be permitted? What are the reasons for your view?

The College is against Direct to Consumer Advertising (DTCA) and strongly encourages the government to prohibit this practise. There is significant research showing that DTCA is harmful to patients and the doctor-patient relationship. The College has a position statement on DTCA and the key points from this statement are set out below[3]:

- Product and health information provided in DTCA is not of sufficient quality to be considered educational.
- DTCA undermines the value of scientific evidence through its misuse and alters the public's perceptions of the safety of prescription medications.
- DTCA increases the likelihood of the consumer requesting the advertised product and/or believing they have a condition, resulting in increased prescribing.
- Unfounded patient demand for a product or diagnosis, caused by DTCA, mars this otherwise beneficial model of health care and creates conflict in the doctor–patient relationship.
- Inappropriate prescribing, triggered by DTCA, can cause harm to consumers' health.
- In addition to the health harms, there are considerable financial costs to the patient and health system because of inappropriate prescribing.
- Individuals with less healthy lifestyles are more likely to be influenced by DTCA and this can lead to this cohort thinking DTCA is a 'magic bullet' to resolve problems of daily life.

Our members also commented on the harms they had witnessed in their own practice:

> *"[The] harm is in the relationship between the GP and the patient when the GP has to explain why the medication advertised on the TV is not appropriate. The relationship between GP and patient is one of trust and if companies are advertising drugs it creates expectations that the doctor then has to manage. We have enough issues trying to dissuade people from antibiotic use, we don't need more drugs to try and explain why they are not the best choice for them."*

[3] https://rnzcgp.org.nz/RNZCGP/Advocacy/Position_statements/Direct_Consumer_Advertising.aspx. Please refer to this statement for a list of references.

"Perfectly well controlled asthmatics requesting an "advertised" product ("Because it is much better") and then not using the spacèr and ending up as an ambulance call and A&E attendance. Harm to patient, cost to the emergency services and cost to DHB."

"As a GP it is very difficult managing the consequences of such advertising with patients who think they may benefit from a medicine that may be inappropriate for their situation and will definitely be more expensive for them / not funded. There is an inherent assumption by the public that newer (and more expensive) medicines are 'better' than existing ones, and that doctors who do not use newer medicines are 'out of date."

Alongside banning DTCA the College would like to see an independent health knowledge hub that patients can access to receive balanced advice about the risks and benefits of different medications.

We hope you find our submission helpful. Should you require any further information or clarification please contact the College's policy team at policy@rnzcgp.org.nz.

Yours sincerely

Bernadette Cornor
Head of Governance and Policy

About general practice and the Royal New Zealand College of General Practitioners

General practice is the medical specialty that treats patients: with the widest variety of conditions; with the greatest range of severity (from minor to terminal); from the earliest presentation to the end; and with the most inseparable intertwining of the biomedical and the psychosocial. General practitioners (GPs) treat patients of all ages, from neonates to elderly, across the course of their lives.

GPs comprise almost 40 percent of New Zealand's specialist workforce and their professional body, The Royal New Zealand College of General Practitioners (the College), is the largest medical college in the country. The College provides training and ongoing professional development for GPs and rural hospital generalists and sets standards for general practice. The College has a commitment to embed the three principles (participation, partnership and protection) of Te Tiriti o Waitangi (Treaty of Waitangi) across its work, and to achieving health equity in New Zealand.

Health equity is the absence of avoidable or remediable differences in health outcomes and access to health services among groups of people, whether those groups are defined socially, economically, demographically, or geographically (WHO). To achieve health equity, we advocate for:

- funding and support to sustain the development of a GP workforce of sufficient capacity to meet population need for access to quality primary medical care, particularly in rural and high need areas.
- a review of the funding model for primary care to ensure that resourcing is allocated equitably across diverse populations with differing needs.
- improved integration of primary, community, and secondary care health and social services which ensures the provision of high-quality services.
- universally accessible free primary health care for children and low-income families, because health inequities begin early and compound over the life course.
- sustained focus on measures to reduce smoking and to increase healthy food options for low-income families.
- a greater focus on the social determinants of health (including labour, welfare, education, housing, and the environment).